

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
TAMPA DIVISION**

OVIS ELLERBEE and JAMES  
ELLERBEE,

Plaintiffs,

v.

Case No. 8:20-cv-1514-T-60AEP

ETHICON, INC. and JOHNSON &  
JOHNSON,

Defendants.

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**ORDER DENYING “DEFENDANTS’ MOTION  
TO EXCLUDE LENNOX HOYTE, M.D.”**

This matter is before the Court on “Defendants’ Motion to Exclude Lennox Hoyte, M.D.,” filed on November 1, 2019. (Doc. 42). Plaintiffs responded in opposition on November 18, 2019. (Doc. 48). Defendants replied to Plaintiffs’ response on November 22, 2019. (Doc. 50). Upon review of the motion, response, reply, court file, and record, the Court finds as follows:

**Background**

This case is one of thousands of similar cases filed since 2010.<sup>1</sup> Plaintiffs Ovis Ellerbee and James Ellerbee sued directly in the Southern District of West

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<sup>1</sup> In the seven MDLs, over 100,000 cases have been filed, approximately 40,000 of which are in the Ethicon MDL. See MDL 2187 (C.R. Bard) Member List of Cases, <https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2187>; MDL 2325 (American Medical Systems) Member List of Cases, <https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2325>; MDL 2326 (Boston Scientific) Member List of Cases, <https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2326>; MDL 2327 (Johnson & Johnson, Ethicon) Member List of Cases, <https://www.wvsd.uscourts.gov/caselist/caseviewlist.aspx?mdl=2327>;

Virginia as part of the multidistrict litigation (MDL) entitled *In re: Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Lit.*, MDL No. 2327. The case was not resolved by the MDL transferee court (“MDL Court”), and on July 1, 2020, it was transferred to this Court.

On November 7, 2006, Ms. Ellerbee was implanted with Ethicon’s TVT-O and Prolift devices at a hospital in Tampa, Florida. Both devices were designed and manufactured by Defendants Johnson & Johnson and Ethicon, Inc. In early 2017, Ms. Ellerbee’s physician surgically removed what Plaintiffs claim to have been mesh located in the bladder mucosa. On February 23, 2017, Ms. Ellerbee underwent a revision/removal procedure and an anterior colporrhaphy. Ms. Ellerbee later had another mesh sling implanted.

On June 24, 2015, Plaintiffs sued directly in the MDL using a short-form complaint, alleging: Negligence (Count I), Strict Liability – Manufacturing Defect (Count II), Strict Liability – Failure to Warn (Count III), Strict Liability – Defective Product (Count IV), Strict Liability – Design Defect (Count V), Common Law Fraud (Count VI), Fraudulent Concealment (Count VII), Constructive Fraud (Count VIII), Negligent Misrepresentation (Count IX), Negligent Infliction of Emotional Distress (Count X), Breach of Express Warranty (Count XI), Breach of Implied Warranty (Count XII), Violation of Consumer Protection Laws (Count XIII), Gross Negligence

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MDL 2387 (Coloplast) Member List of Cases, <https://www.wvsc.uscourts.gov/caselist/caseviewlist.aspx?mdl=2387>; MDL 2440 (Cook Medical) Member List of Cases, <https://www.wvsc.uscourts.gov/caselist/caseviewlist.aspx?mdl=2440>; and MDL 2511 (Neomedic) Member List of Cases, <https://www.wvsc.uscourts.gov/caselist/caseviewlist.aspx?mdl=2511>.

(Count XIV), Unjust Enrichment (Count XV), Loss of Consortium (Count XVI), Punitive Damages (Count XVII), and Discovery Rule and Tolling (Count XVIII).

In the motion before this Court, Defendants raise various *Daubert* challenges to the proposed testimony of Lennox Hoyte, M.D. Dr. Hoyte has previously been qualified as an expert witness in pelvic mesh MDL litigation. *See, e.g., Katsiafas v. C. R. Bard*, 2:19-cv-822-FtM-60MRM, 2020 WL 1808895, at \*2-4 (M.D. Fla. Apr. 9, 2020), *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2018 WL 4220671, at \*3–5 (S.D.W. Va. Sept. 5, 2018); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 622–27 (S.D.W. Va. 2013). In fact, Dr. Hoyte testified in at least one of the C.R. Bard bellwether trials, where it appears he offered many of the same expert opinions that Defendants seek to exclude. That trial resulted in a jury verdict, affirmed by the Fourth Circuit Court of Appeals, in favor of the plaintiff. *See In re C.R. Bard, Inc., MDL No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913, 930 (4th Cir. 2016) (reviewing the expert evidence presented by the plaintiff as to the design defects, including the testimony of Dr. Lennox Hoyte).

### **Legal Standard**

An expert witness may testify in the form of an opinion if “(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.” Fed. R. Evid. 702; *see also Daubert v. Merrell Dow*

*Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993). “The party offering the expert testimony bears the burden of establishing, by a preponderance of the evidence, the expert's qualification, reliability, and helpfulness.” *Payne v. C.R. Bard, Inc.*, 606 F. App’x 940, 942 (11th Cir. 2015) (citing *United States v. Frazier*, 387 F.3d 1244, 1258 (11th Cir. 2004) (en banc)).

Functioning as a gatekeeper, the district court plays an important role by ensuring that all scientific testimony is relevant and reliable. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 601. Although *Daubert* references specific factors for the district court to consider when evaluating relevancy and reliability, “[t]he inquiry to be undertaken by the district court is a flexible one focusing on the principles and methodology employed by the expert, not on the conclusions reached.” *Id.* at 601-02 (internal quotations and citations omitted); *see Hanna v. Ward Mfg., Inc.*, 723 F. App’x 647, 649 (11th Cir. 2018) (outlining the criteria for the admissibility of expert witness testimony). Essentially, the Court is simply asked to determine if the evidence “rests on a reliable foundation and is relevant.” *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014) (quoting *Daubert*, 509 U.S. at 597).

In several *Daubert* motions – including the instant motion – “a specific scientific methodology comes into play, dealing with differential diagnoses or etiologies.” *See In re C.R. Bard*, 948 F. Supp. 2d at 601. As the MDL court explained, a differential diagnosis is a scientific technique where the expert identifies the cause of a medical problem by “eliminating the likely causes until the most probable one is isolated.” *See id.* (quoting *Westberry v. Gislaved Gummi AB*,

178 F.3d 257, 262 (4th Cir. 1999)). “A reliable differential diagnosis passes scrutiny under *Daubert*. An unreliable differential diagnosis is another matter” and may be excluded. *Id.* However, a district court should not exclude a medical expert’s opinions if he or she has “failed to rule out every possible alternative cause of a plaintiff’s illness.” *Id.* (quoting *Westberry*, 178 F.3d at 265-66). Instead, “the alternative causes ... affect the weight that the jury should give the expert’s testimony and not the admissibility of that testimony,” unless the expert is unable to offer any explanation for his or her causation opinion in light of the alternative causes offered by the opposing party. *Id.* (quoting *Westberry*, 178 F.3d at 265-66).

### **Analysis**

Plaintiffs offer Dr. Hoyte as an expert in the areas of urogynecology, female pelvic medicine, and reconstructive surgery, and he has been designated to provide expert testimony. Here, Defendants make no argument that Dr. Hoyte is unqualified to serve as an expert. However, they seek to exclude certain opinions concerning: (1) specific causation, including that Defendants’ products caused or contributed to Ms. Ellerbee’s purported injuries; (2) safer alternatives to Defendants’ products; (3) shrinkage, scarring, and mesh contraction; and (4) Ms. Ellerbee’s future prognosis.

### ***Opinions on Specific Causation***

Defendants seek to exclude Dr. Hoyte’s opinions concerning specific causation as unsupported by the record and based on an unreliable methodology. Defendants specifically argue that Dr. Hoyte’s opinions are based on a deficient and unreliable

differential diagnosis because he failed to address multiple alternative causes for each of the medical conditions he claims are attributable to the products.

Upon review of the record, including Dr. Hoyte's expert report and deposition, the Court finds that Dr. Hoyte has conducted a "sufficiently reliable differential diagnosis" to support his case-specific opinions. *See* (Docs. 42-9; 42-10); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 627. In this case, Dr. Hoyte discusses other potential causes, such as Prolene sutures, for Ms. Ellerbee's injuries and rules them out.

To the extent Defendants contend there are other possible alternative explanations, or that Dr. Hoyte's analysis relies too much on temporal proximity, these arguments related to any perceived faults in Dr. Hoyte's differential diagnosis are better suited for cross-examination and do not affect admissibility. Accordingly, the Court finds that Dr. Hoyte's specific causation opinions, including his opinions on design defects, are supported by the record, sufficiently reliable, and admissible. Defendants' request to exclude these opinions is denied.

### ***Opinions on Safer Alternatives to Defendants' Products***

Defendants contend that Dr. Hoyte's opinions regarding safer alternatives are not admissible because he opines on safer alternative procedures rather than safer alternative products. The Court disagrees. Dr. Hoyte's opinions on safer alternatives are relevant to this litigation. Dr. Hoyte specifically opines, for example, that a "retropubic synthetic sling" would have been a safer alternative to Defendants' products "because the retropubic sling arms do not puncture and scar into the levator ani muscles causing pain." (Doc. 42-9 at 34). In other pelvic mesh

product liability cases, plaintiffs have been able to present substantially similar expert evidence on safer alternative designs, including that the product could have been designed with “polypropylene mesh with larger pores,” or “rounder, thinner arms,” or that the mesh could have been constructed with “native tissue.” *See Dalton v. C. R. Bard, Inc.*, No. 3:19-CV-2484-D, 2020 WL 1307965, at \*10-11 (N.D. Tex. Mar. 19, 2020); *Dahse v. C. R. Bard, Inc.*, No. 2:12-CV-02701, 2016 WL 7155770, at \*4 (S.D. Va. Dec. 7, 2016); *Cisson v. C. R. Bard, Inc.*, No. 2:11-CV-00195, 2013 WL 5700513, at \*1, \*4 (S.D.W. Va. Oct. 18, 2013), *aff’d sub nom. In re C. R. Bard, Inc., MDL No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913 (4th Cir. 2016). Consequently, Defendant’s request to exclude Dr. Hoyte’s opinions as to safer alternatives is denied.

### ***Opinions on Shrinkage, Scarring, and Mesh Contraction***

Defendants also seek to exclude Dr. Hoyte’s opinions concerning alleged shrinkage, scarring, and mesh contraction. Specifically, Defendants claim that there is no reliable evidence to support these opinions because the record does not reflect that Dr. Hoyte personally examined Ms. Ellerbee’s explanted pelvic mesh and observed these conditions.

As an urogynecologist, Dr. Hoyte has “significant experience with pelvic repair . . . products,” and he has “personally examined hundreds of patients with mesh complications.” *In re C.R. Bard*, 948 F. Supp. 2d at 627. He has reviewed Ms. Ellerbee’s medical records and performed a sufficiently reliable differential diagnosis, in addition to personally examining Ms. Ellerbee. *See* (Doc. 42-9) (“I

personally examined Ovis Ellerbee on August 8, 2019 ...”). It is clear that Dr. Hoyte is qualified “by knowledge, skill, experience, or education” to offer opinions as to shrinkage, scarring, and mesh contraction. *See* Fed. R. Evid. 702. To whatever extent Defendants feel compelled to challenge Dr. Hoyte’s opinions, they are free to raise such arguments on cross-examination. The Court denies Defendants’ request to exclude these opinions.

### ***Opinions on Future Prognosis***

Defendants seek to exclude Dr. Hoyte’s opinions regarding Ms. Ellerbee’s future prognosis because they are speculative. Specifically, Defendants argue that Dr. Hoyte himself states that “the prognosis for [Ms. Ellerbee’s] groin and leg pain as well as her entry dyspareunia is uncertain, given that she has remaining portions of the shrunken, scarred-in mesh irritating her obturator, levator ani, adductor, groin and ischiorectal fossa tissues.” (Doc. 42-9 at 34). Opinions about future prognosis are always, by their very nature, somewhat uncertain. Dr. Hoyte’s recognition of this uncertainty and potential variability does not cut against the admissibility of his opinions. District courts – including the MDL Court – have frequently concluded that such opinions are sufficiently reliable to move forward. *See In re Ethicon, Inc. Pelvis Mesh Repair Sys. Prod. Liab. Lit.*, MDL No. 2327, 2017 WL 2214909, at \*2 (S.D.W. Va. May 18, 2017).

### **Conclusion**

Upon a review of the record in this case, the Court finds that Dr. Hoyte’s challenged opinion is sufficiently reliable and relevant to allow it to be heard at

trial. If Ethicon believes the Dr. Hoyte's opinion about Ms. Ellerbee's future prognosis is deficient, Ethicon may attack that opinion on cross-examination.


Accordingly, Defendants' request to exclude these opinions is denied.

Accordingly, it is

**ORDERED, ADJUDGED, and DECREED:**

"Defendants' Motion to Exclude Lennox Hoyte, M.D." (Doc. 42) is **DENIED**.

**DONE and ORDERED** in Chambers, in Tampa, Florida, this 19th day of August, 2020.



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**TOM BARBER**  
**UNITED STATES DISTRICT JUDGE**